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Application of Regulation (EU) No 528/2012 ("BPR")

Proposal for designing the procedure for the authorisation of biocidal products for in-situ water treatment systems

As of: 06 March 2017

I. Foreword

When the BPR came into force on 1 September 2013, for the first time active substances and/or biocidal products produced in situ were included in the scope of application of European biocides law. Assistance for the regulatory classification of in-situ systems ("ISS")[1] was already provided by the competent authorities of the Member States and the EU Commission in the document CA-March15-Doc.5.1-Final, revised on 23 June 2015 and further specified by additional guidelines since then.[2]

The focus was initially on redefining active substances and ensuring the inclusion of the redefined active substances in the work programme of the EU partly by corresponding notifications.[3] The enterprises concerned and especially the manufacturers of water treatment devices accepted the challenges created and took the necessary action.

Irrespective of the legal requirements of the BPR, however, there are still uncertainties with regard to the specific requirements for the future product authorisation procedures for ISS, which were also not clarified by the existing guidelines and documents.

The EU Commission advised us in this context to develop a specific proposal for structuring the future product authorisation procedures for ISS, to seek coordination on this especially with the competent authorities in Germany and the Netherlands, and to contribute this proposal to further consultations.

We have followed this advice and we set out a summary of our proposal below.

[1] Understood as a combination of active substance, precursor and product type in line with CA-March15-Doc.5.1-Final, revised on 23 June 2015 (see p6 of this).
[2] See for example CA-May15-Doc.5.1.a – Final; CA-Nov15-Doc.5.5 – Final_Rev1; CA-May16-Doc.5.1 – Final.
[3] See https://echa.europa.eu/documents/10162/17287015/biocides_substances_redefined_identity_en.pdf/.

II. Status quo

The general prerequisites for granting authorisation for biocidal products are laid down in Article 19 BPR. The requirements listed there also apply in principle to the authorisation of biocidal products used for in-situ production of active substances as precursors or which are generated by ISS without the use of precursors. It already follows from Article 19(2) BPR that authorisation only comes into question if it can be proven that the biocidal product to be assessed meets a number of fixed criteria when used as authorised.

Due to the large number of ISS coming into question[4], within this proposal we use the ISS "Active Chlorine generated from Sodium Chloride by Electrolysis" as an example for specifying individual aspects, focusing only on the product types ("PT") 2, 4 and 5 according to Annex V to the BPR. Regardless of this, however, the fundamental special features in connection with ISS are to be described and specific suggestions are to be made for designing the corresponding product authorisation procedures, so that these can also be applied without restriction to other ISS and/or product types.

Currently no active substance approval has been granted for an ISS although numerous procedures are already subject of active substance approval procedures.[5] A complete overview of the ISS currently notified is available on the ECHA website[6].

The publication of an active substance approval for the ISS "Active Chlorine generated from Sodium Chloride by Electrolysis" for the use in PTs 2, 4 and 5 is expected in 2018 at the earliest according to current estimates.[7] Thus this ISS – probably in addition to the active substance approval for ozone – is the first ISS applicable to water treatment for which active substance approval is expected. According to Article 9(1)(a) BPR, the decision on active substance approval will specify the date of approval, which also sets the deadline for applying for product authorisation (see Article 89(3) BPR).

Regardless of the ongoing active substance approval procedures for ISS, the enterprises concerned should already take the first binding steps with regard to the subsequent product authorisation. For example, a legally binding decision must be made about joining consortia forming in the market or about developing alternative approaches. This applies especially since according to Article 17(1) BPR only approved biocidal products are allowed to be placed on the market and used. Further clarifications of the content and requirements of the product authorisation

[4] See the list in https://echa.europa.eu/documents/10162/17287015/biocides_substances_redefined_identity_en.pdf/.

[5] See ECHA active substance list

[6] The list of successful notifications can be found at https://echa.europa.eu/documents/10162/17287015/list_compliant_notifications_en.pdf/e39a07ea-52dd-4562-a8e5-eab6be898312. The complete active substance list including the post-notifications made can be found at https://echa.europa.eu/information-on-chemicals/biocidal-active-substances?p_p_id=echarevbiocides_WAR_echarevbiocidesportlet&p_p_lifecycle=1&p_p_state=normal&p_p_mode=view&p_p_col_id=column-1&p_p_col_pos=1&p_p_col_count=2&_echarevbiocides_WAR_echarevbiocidesportlet_javax.portlet.action=searchBiocidesAction.

[7] According to the work program of the biocidal products committee of ECHA, the in-situ system "Active Chlorine generated from Sodium Chloride by Electrolysis" is on the agenda at the 23rd BPC meeting on 11-15 December 2017. (https://echa.europa.eu/documents/10162/17287015/wp_active_substance_approvals_2016_17_en.pdf)

procedure are thus necessary both for producers of precursors and for operators of ISG to ensure the smoothest possible implementation of the BPR for ISS. Similarly, this also applies to the producers of ISG, insofar as these producers also come into question as authorisation holders, at least optionally.[8]

III. Initial situation

The proposal below is based on the following cornerstones:

1. Understanding of terms

The abbreviation "**ISS**" designates the specific active substance system corresponding to the redefinition in CA-March15-Doc.5.1-Final, revised on 23 June 2015, i.e. the combination of precursor and active substance, possibly supplemented by references to the process (e.g. electrolysis, acidification).

Separately from this, the term "**device**" or "**ISG**" designates the entirety of plant technology used to generate the active substances from precursors and/or to generate biocidal products from ubiquitous raw materials and which as such is not or cannot be the subject of an authorisation decision under biocides law (see Article 17 BPR).

Otherwise the terms are used according to the definitions in Article 3(1) BPR and in harmony with the understanding of terms according to the CA documents referred to.[9]

2. Requirements under BPR and according to previously coordinated CA documents

According to Article 17(1) BPR, only biocidal products within the meaning of Article 3(1)(a) BPR are subject to an authorisation obligation. Authorisation can thus only refer, according to Article 17(3) BPR, to a biocidal product or a biodical product family.

In light of this, CA-March15-Doc.5.1-Final clarified the following:

- The marketability and/or usability of precursors to be marketed with a biocidal intended purpose requires both a corresponding active substance approval and a product authorisation based upon it;
- In principle, every interested market participant and/or user can conduct active substance approval and product authorisation procedures for specific ISS;
- For ISS based on ubiquitous raw materials or on precursors marketed without a biocidal intended purpose, in any case the operator of the corresponding ISG will have to ensure adequate product authorisation unless other players in the supply chain (such as producers of ISG) take on this task;
- Harmonised technical standards (EN standards, e.g. EN 973 chlorine, EN 14805 sodium chloride) come into question for determining ISS with regard to the active substance approval procedure. They can also be

[8] See for example CA-May15-Doc.5.1.a – Final, page 6.
[9] See especially CA-March15-Doc.5.1- Final - Substances generated in situ.

used in assessing technical equivalency to avoid potential systemic distortions between active substance approval and subsequent product authorisation.[10]

In addition, individual cases were handled in the framework of separate guidelines, but without going into the details of the product authorisation procedure:

- Ozone made from air, water or oxygen, insofar as this is marketed without an intended purpose as a biocide.[11]
- Free radicals made from surrounding water or surrounding air.[12]

Due to currently ongoing transitional periods according to Articles 89 and 93 BPR there is at least temporarily some legal security for the companies in the field of water treatment. Insofar as applications for active substance approval for ISS have already been filed and are being processed or at least the necessary notifications have been made, these can be used in accordance with the BPR.[13] After conclusion of the active substance approval procedures, the transitional provisions of the BPR also guarantee that if there is timely application for a product authorisation, continued legally compliant use is also ensured for the duration of the approval procedure.

From Article 17 BPR it follows that a product authorisation does not have to be applied for individually by every user. It is enough that authorisation be granted for the biocidal product in question and that the product be used as specified in the authorisation. In particular, producers of devices are not legally obliged to apply for product authorisation.[14]

3. Objectives and proposal

The inclusion of ISS and their use in the scope of the BPR is only partly acknowledged in the procedural provisions of the regulation. The usual understanding of a two-part evaluation process staggered over time consisting of active substance approval and product authorisation creates specific issues for ISS which need to be clarified.

Unlike with ordinary biocidal products, which normally contain one or more previously approved active substances, ISS are characterised in that the biocidal products subject to authorisation do not act biocidally themselves as they contain no active substance (as with precursors, see Article 3(1)(a), 1st indent BPR), or are in principle identical to the previously approved active substance (as with ISS with no tradable precursor, see Article 3(1)(a), 2nd indent BPR).

However, the BPR also determines for ISS that solely the active substance approval and product authorisation are the prerequisites for the marketability and usability of the biocidal product to be assessed. The requirements for ISS here should neither be stricter nor more lenient than those for other biocidal products.

[10] See CA-May15-Doc.5.1 – Final, page 4.
[11] See CA-May15-Doc.5.1 – Fina., "The case of ozone"
[12] See CA-Sept15-Doc.5.1.b-Final "The case of free radicals"
[13] Any additional national rules to be observed, in Germany under the Biocides Notification Regulation for example, are not to be taken into consideration here.
[14] See CA-Nov15-Doc.7.3 „Article 95 listing and in situ generation – the case of device manufacturers and users"

But at the same time it should be guaranteed for ISS that product authorisations ensure the general marketability of the relevant biocidal products. This makes it necessary to create a procedure which enables safe use of biocidal products, either generated in situ or used for in situ generation, in a large number of individual applications in compliance with the objectives of the BPR.[15]

From the perspective of the device-manufacturing industry and the operators of ISG, in view of the currently approx. 1.5 million devices in operation for the treatment of drinking water and swimming pool water, a practical solution is essential.

The aim of our proposal is to properly implement for ISS, too, the interactions envisaged between active substance approval and product authorisation in the BPR. The proposed solution[16] in CA-March15-Doc.5.1- Final is to welcome from the perspective of the device-manufacturing industry.

The approach should be supplemented with considerations which enable tangible synergies for ISS to be leveraged.

- As far as the active substance and the biocidal product are to be considered equivalent (as with ISS without a tradable precursor, see Article 3(1)(a), 2nd indent BPR), even taking into account the requirements of the BPR, there are ultimately no further authorisation requirements as safe use has already been proven as part of the active substance approval.
- If active substances produced by using ISS are also available on the market as industrially produced active substances (e.g. active chlorine), assessment parameters for the same individual applications should be uniform within the objectives framework set by the BPR.[17]

IV. Possible cornerstones of a product authorisation procedure for ISS working with tradable precursors

Starting from the above considerations, the following cornerstones of a product authorisation procedure for tradable precursors to generate ISS can be derived:

1. The data requirements for the product authorisation procedure according to Annex III to the BPR refer solely to the biocidal product to be authorised, i.e. the precursor. To assess the authorisation prerequisites according to Article 19 BPR, however, for ISS it is mainly

[15]Otherwise, i.e. with authorisation based on the individual usage, key harmonisation effects of the BPR would be excluded for ISS. Thus for example an EU-wide authorisation or mutual recognition would be virtually ruled out if for example local water quality, which is not available in the same quality in other Member States, were to be defined as a condition of use.

[16] There it says on page 4: "It is acknowledged that a comparison of the chemical composition and hazard profile of the in situ generated active substances would be technically difficult, if not impossible, to achieve, as it may in particular be challenging to establish a reference source. It might however be possible to establish technical specifications or to refer to existing standards, such as CEN standards. These technical specifications could be established either for the active substance itself or its precursors, as appropriate, at the time of the substance approval. It will then have to be ensured and demonstrated at the time of product authorisation that the precursors or the active substances, as appropriate, meet the agreed specifications."

[17]This does not rule out different aspects being acknowledged in the risk assessment. If similar usage-related issues arise, these should also be assessed consistently. Insofar as in-situ production has no effects on the parameters to be assessed, no deviating assessments are justified either.

a matter of the intended biocidal effect and hence ultimately the generated ISS itself, and thus primarily the findings of the active substance approval procedure. It should therefore be clarified that in accordance with the basic concept of the BPR the findings of the active substance approval are basically adequate for supporting a subsequent product authorisation procedure for the precursor.

2. For this, the requirements for evidence according to Article 19(1)(c) BPR must be further specified. To meet the requirement of proof of technical equivalence (see fig. 2.5 of the table to Title 1 or 2 of Annex III BPR), the specific in-situ generation should not be seen as a production process, as otherwise separate evidence would have to be provided for each individual application and thus the authorisation capacity of precursors[18] would de facto be eliminated.

   Instead, it should be specified that in-situ production observing certain fixed parameters with recourse to acknowledged and established (harmonised) technical standards is deemed to be one and the same production process.

   If and as long as compliance with the corresponding requirements is proven, it can be assumed that the production process is the same. Similarly, the requirement of proof of technical equivalency should not depend on the site of application of the precursor or the ISG used, insofar as defined parameters are observed in accordance with technical and legal normative regulations.

3. Similarly, for the purposes of the product authorisation procedure taking into account Article 19(2)(a) BPR, criteria should be determined for ISS which define realistic worst-case conditions without depending on a usage-specific case-by-case basis. Due to applicable legal requirements and existing accepted technical regulations, ISG already comply today with fixed parameters which should not be deviated from, even for the purpose of a worst-case appraisal.

4. Outside of established regulations, too, specific aspects may have to be observed in the product authorisation procedure. This applies to by-products from the in-situ process and their retention in drinking or swimming pool water, for example, as well as to the disinfection by-products arising during disinfection and their retention in the water.

5. However, the resulting requirements should be structured so that they enable reliable provision of the requested data and a robust decision in the authorisation procedure on which the later marketing and use of the approved precursor[19] can also be based, independently of locally differing or time-fluctuating water quality, pollution or other environmental conditions.

[18] And also of ISS without tradable precursors.

[19] The ECHA proposal on treating disinfection by-products highlights the need for a pragmatic approach (https://echa.europa.eu/documents/10162/15623299/bpr_guidance_vol_v_dbp_en.pdf/a57a2905-923a-5aa3-ead8-45f5c5503daf).

6. It appears both appropriate and essential to determine the necessary parameters by defining a test water as a basis for the provision of data (in the relevant PT).[20] For the purposes of the approval procedure it should be enabled using a test water thus defined which also fits the stipulations of Article 19(2) BPR, to provide the required proof according to Article 19(1)(b) BPR.

7. When defining test parameters, it should also be taken into account that ISG must meet standardised regulations. There is no legal basis nor any need according to the BPR for further consideration of device-specific details in the product authorisation procedure. The BPR cannot and is not intended to cover device authorisations. For the purposes of product authorisation, therefore, the stipulation and proof that the biocidal product is used by an ISG corresponding to the defined technical parameters should be sufficient. This is also appropriate. The effects on target organisms, on the health of humans and animals and on the environment depend primarily on the characteristics of the water to be treated and the proper, standard-compliant operation of the ISG and not on the device characteristics. This fact can be taken into account through standardised test parameters.

8. By recourse to the existing legal and technical requirements, it should be guaranteed that future developments regarding the use of disinfection procedures can be considered without BPR targets being neglected. Such future developments can be the result of *inter alia* a (desirable) further pan-European harmonisation of the statutory and normative requirements for drinking water hygiene. As a consequence, technical/content-related contradictions at the interface of different areas of competence can also be avoided.

9. Linking the approval procedure with mandatory pre-established requirements of legal and technical standards enables the public concerned and the competent authorities to precisely monitor compliance with use conditions. Also, active participation by the Member States' authorities responsible for implementing the BPR and/or ECHA or the EU Commission on the testing and refinement of the relevant technical standards would then be expedient in order to contribute the resulting know-how from the authorisation procedures to the further development of the generally accepted state of the art.

These requirements can ensure that a proper assessment corresponding to the BPR can take place in an approval procedure.
Approval thus granted would supplement compliance with existing, comprehensive European and national regulations such as those on the disinfection of drinking water (PT 5), the disinfection of surfaces in contact with food and drinking water (PT 4), and disinfection of swimming pool water (PT 2).
Also, the use of precursors for purposes of in-situ manufacturing is safeguarded and guaranteed by regulations. Finally, anticipated deficits in implementation and enforcement (such as for existing plants) would also be avoided.

[20] The ECHA paper on DBP contains the corresponding considerations (https://echa.europa.eu/documents/10162/15623299/bpr_guidance_vol_v_dbp_en.pdf/a57a2905-923a-5aa3-ead8-45f5c5503daf).

The monitoring of proper device/system operation could then focus on the following core points:

1. Compliance with use conditions according to relevant technical standardisation and corresponding to the instructions of the ISG producer.
2. Use of a BPR-authorised precursor by the operator.
3. Compliance with maintenance requirements arising from legal requirements, standardisation and instructions.

V. Conclusion and outlook

This proposal can ensure the application of BPR for ISS.

The BPR in principle does not aim to make each and every use of a biocidal product the subject of a separate authorisation procedure. Instead, an authorisation granted is intended to ensure the marketability of the biocidal product and define the requirements for use. The requirements for the authorisation procedure for ISS must also not be overextended, to avoid authorisations being granted on a case-by-case basis.

A market-side refinancing of case-by-case, device- or usage-specific authorisation procedures is ruled out. Without appropriate designing of the authorisation procedure, numerous device manufacturers would probably leave the market. The innovative power of an entire industry would therefore be eliminated in practical terms.

Neither on the side of the precursor industry nor on the side of the operators of in-situ systems is there a business interest in a competitive structuring of the market solely driven by the regulatory stipulations of the BPR. The approval procedure in this respect should not lead to distortions in the market, which are likely if there are case-by-case product authorisation procedures mainly because of the differing procedure durations and thus availability dates, since ISG operators would lack the necessary planning certainty to make investment decisions.

In the case of producer- or device-specific authorisations, according to the current assessment there is no legally secure way of ensuring BPR-compliant continued operation of existing plants. With over 1.5 million existing plants, this is a serious problem which can greatly undermine confidence in the in-situ procedures.

Yours sincerely,

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06 March 2017

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We are not only a registered stakeholder for the implementation of the BPR. We are mainly focused on the impacts and requirements of the BPR on water and waste water treatment by in-situ generated active substances. Our member companies are actively involved in the preparation of several dossiers for active substances approval as well as biocidal product authorisation.